PULSE OXIMETER (FOX-3)
User Manual (English)

Instructions to User

Dear users, thank you very much for purchasing the Pulse Oximeter.
This manual is written and compiled in accordance with the council directive MDD93/42/EEC for medical devices and harmonized standards. In case of modifications and software upgrades, the information contained in this document is subject to change without notice.
The manual describes, in accordance with the Pulse Oximeter's features and the requirements, main structure, functions, specifications, correct methods for transportation, installation, usage, operation, repair, maintenance and storage, etc. As well as safety procedures to protect both the users and equipment. Refer to the respective chapter for details.
Please read the user manual very carefully before using this equipment. These instructions the operating procedures to be followed strictly. Failure to follow these instructions can cause measuring abnormality, equipment damage and human injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, personal injury and equipment damage due to user's negligence of the operating instructions. The manufacturer's warranty service does not cover such faults.
Owing to the forthcoming renovation, the specific products you received may not be totally in accordance with the description of this User Manual. We would sincerely regret for that.
This product is medical device, and can be used repeatedly.

WARNING:

- **Discomfort or pain may appear if using the device ceaselessly, especially for the microcirculation barrier patients. It is recommended that the sensor should not be applied to the same finger for over 2 hours.**
- **For the special patients, there should be a more prudent inspecting in the placing process. The device cannot be clipped on the edema and tender tissue.**
- **The light (the infrared is invisible) emitted from the device is harmful to the eyes, so the user and the maintenance man, cannot stare at the light.**
- **Testee cannot use enamel or other makeup.**
- **Testee's fingernail cannot be too long.**
- **Please refer to the correlative literature about the clinical restrictions and caution.**
- **This device is not intended for treatment.**

1. Safety

1.1 Instructions for Safe Operations

- Check the main unit and all accessories periodically to ensure that no visible damage that may affect patient's safety and monitoring performance. It is recommended that the device should be inspected weekly at least. When there is obvious damage, stop using the device.
- Necessary maintenance must be performed by qualified service engineers only. Users are not permitted to maintain it by themselves.
- The oximeter cannot be used together with the device not specified in user's manual. Only the accessory that is appointed or recommendatory by manufacture can be may be used with this device.
- The product is calibrated before leaving the factory.

1.2 Warning

- Explosive hazard - DO NOT use the oximeter in environment with inflammable gas such as some ignitable anesthetic agents.
- DO NOT use the oximeter while the patient is being measured by MRI or CT.
- DO NOT strand the lanyard in order to avoid device drop and damage. The lanyard is made of non-sensitive material. Please do not use lanyard if the user is allergic to lanyard. Do not enwind neck with lanyard in order to avoid accident.
- The person who is allergic to rubber cannot use this device.
- The disposal of scrap instruments and its accessories and packing (including batteries, packing box, foams, and color box) should follow local laws and regulations.
- Please check the packing before use to make sure the device and accessories are totally in accordance with the packing list, or else the device may have the possibility of working abnormally.
- Please choose the accessories which are appointed or recommended by the manufacturer for avoiding device damage.
- Please don't measure this device with functional tester for the device's related information.

1.3 Attentions

- Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- If the oximeter gets wet, please stop operating it.
- When it is carried from cold environment to warm or humid environment, please do not use it immediately.
- DO NOT operate keys on front panel with sharp materials.
- High temperature or high pressure steam disinfection of the oximeter is not permitted. Refer to User Manual in the relative chapter for instructions of cleaning and disinfection.
- Do not have the oximeter immerged in liquid. When it needs cleaning, please wipe its surface with medical alcohol by soft material. Do not spray any liquid on the device directly.
- When cleaning the device with water, the temperature should be lower than 60℃.
- The fingers which are too thin or too cold may affect the measure accuracy, please clip the thick finger such as thumb and middle finger deeply enough into the probe.
- The oximeter probe which is optional can be used to children.
- The update period of data is less than 5 seconds, which is changeable according to different individual pulse rate.
- The waveform is normalized.Please read the measured value when the waveform on screen is equably and steady-going, Here this measured value is optimal value. And the waveform at the moment is the standard one.
- If some abnormal conditions appear on the screen during test process, pull out the finger and reinsert to restore normal use.
- The device has normal life for three years since the first electrified use.
- The device has alarm function, this function can either be paused, or closed (default setting) for good. Please check the chapter 6.1 as reference.
- The device has the function of beyond limit alarm. When the measure data is beyond the highest or lowest limit, the device would start alarm automatically on the premise of the alarming function is on.
- The device a maybe not fit for all patients. If you are unable to receive approving measure, discontinue use.
- Do not contort or drag the wire of the device.

2. Overview

The pulse oxygen saturation is the percentage of HbO_2 in the blood, so-called the O_2 concentration in the blood. It is an important bio-parameter for the respiration. A number of diseases relating to respiratory system may cause the decrease of SpO_2 in the blood, furthermore, some other causes such as the malfunction of human body's self-adjustment, damage during surgery, and the injuries caused by some medical checkup would also lead to the difficulty of oxygen supply in human body, and the corresponding symptoms human's life. Therefore, prompt information of patients SpO_2 is of great help for the doctor to discover the potential danger, and is of great importance in the clinical medical field.
The Pulse Oximeter is in small volume, low power consumption, convenient in operation and portable. With high-definition display screen, the device is concise and fashion. It is only necessary for patient to put one finger into probe for diagnosis, and the display screen will directly show the SpO_2 value, pulse rate value, Perfusion Index value and pulse waveform with the high veracity and repetition.

2.1 Features

A Ultra-thin design, concise and fashion.
B Small in volume, light in weight and convenient in carrying.
C Low power consumption.
D Display direction can be changed automatically, easy to view.
E Perfusion index measure.

2.2 Major Applications and Scope of Application

The Pulse Oximeter can be used in measuring the pulse oxygen saturation, pulse rate, and perfusion index through finger. The product is fit for family, hospital, Oxygen Bar, community healthcare, physical care in sports (it can be used before or after doing sports and it is not recommended to use the device during the process of having sports) and etc.

⚠**The problem of overrating would emerge when the patient is suffering from toxicosis which caused by carbon monoxide, the device is not recommended to be used under this circumstance.**

2.3 Environment Requirements

Storage Environment
a) Temperature : - 10℃ ~ 40℃
b) Relative humidity : 15%RH~80%RH
c) Atmospheric pressure :50 ~ 106 kPa
Operating Environment
a) Temperature : 5℃ ~ 40℃
b) Relative Humidity: ≤80%
c) Atmospheric pressure : 500 ~ 1060 hPa

3. Principle

Principle of the Oximeter is as follows: An experience formula of data process is established taking use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive Hemoglobin (Hb) and Oxyhemoglobin (HbO_2) in glow & near-infrared zones. Operation principle of the instrument is: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning & Recording Technology, so that two beams of different wavelength of lights can be focused onto human nail tip through perspective clamp finger-type sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown on screen through treatment in electronic circuits and microprocessor.

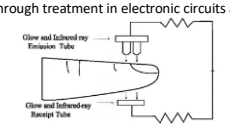


Figure 1 Operating principle

4 Technical Specifications

4.1 Main Performance

- SpO_2 value display.
- Pulse rate value display, bar graph display.
- Pulse waveform display.
- Perfusion index value display.
- Charge function: lithium battery is the power supply and can be charged up time and again.
- Low-power indication: low-power indication symbol appears before working abnormally which is due to low-power.
- Automatic power-off when there is no finger in device under measure interface in 5 seconds.
- The display direction can be changed.
- Pulse sound indication.
- With alarm function.
- With SpO_2 value and pulse rate value record function.
- The record data can be uploaded to the computer.
- It can be connected with oximeter probe.

4.2 Main parameters

a. **Measurement of SpO_2**
Measuring range: 0% ~ 99%
Accuracy: 70 ~ 99%: ±2%; below 70%: unspecified.
b. **Measurement of pulse rate**
Measuring range: 30bpm ~ 250bpm
Accuracy: 30bpm ~ 100bpm: ±2bpm; 101bpm ~ 250bpm: ±2%
c. **Perfusion index**
Range: 0% ~ 20%
d. **Resolution**
SpO_2: 1%, Pulse rate: 1bpm
e. **Measurement performance in Weak Filling Condition**
SpO_2 and pulse rate can be shown correctly when pulse-filling ratio is 0.4%. SpO_2 error is ±4%; pulse rate error is ±2 bpm or ±2% (select larger)
f. **Resistance to surrounding light**
The deviation between the value measured in the condition of man-made light or indoor natural light and that of darkroom is less than ±1%.
g. **Power supply requirement:** 3.6V DC ~ 4.2V DC
h. **Optical sensor**
Red light (wavelength 660 nm, 6.65 mW)
Infrared (wavelength is 905 nm, 6.75 mW)
i. **Adjustable alarm range**
SpO_2: 0% ~ 100%
Pulse Rate: 0bpm ~ 254bpm

5 Installation

5.1 View of the Front Panel

Figure 2 Front view

5.2 Lanyard installation

a. Put the thinner side of the lanyard through the hole.
b. Put the wider side of the lanyard through the thinner side which has been put through the hole, then tighten it.

5.3 Probe installation

a. Open the USB cover, inserting the probe in to the USB port of the pulse oximeter.
b. Insert the finger into the probe (the side with finger sign and the nail should be in the same side). The connected probe could work normally when the luminescent tube in the device doesn't emit red light.

⚠**In order to ensure device life and measure accuracy, external probe is limited to the matching model, and can't be replaced by other model. Or else the device will be damaged or usage is affected.**

5.4 Accessories

- Lanyard
- User manual
- Power adapter (optional)
- Data line
- Disk (PC software)
- Oximeter Probe (optional)

6 Operating Guide

6.1 Application Method

6.1.1 Measurement

a. Insert the finger into the probe of the device
b. Long press button the probe of the device
c. Do not shake the finger and keep the patient in a stable state during the process
d. The data can be read directly from the display screen in the measuring interface.

6.1.2 Lay Finger

The right method of laying finger is as figure 3

Figure 3

⚠**Fingernails and luminescent tube should be on the same side.**

⚠**Automatic power-off when there is no finger in device in 5 seconds.**

6.1.3 Pause Alarm

a. Alarm includes the alarm of measure data's going beyond the limits, the alarm of low-power, and the alarm of finger out.
b. In the measuring interface, if the alarm function is on, during the period of alarming, alarm can be suspended by short pressing the button, but the function will be renewed in about 60 seconds.
c. If you want to turn off the alarm, you should enter the menu for operation. Please refer to chapter "Alarm setting" for detail.

6.1.4 Change Display direction

The device could change display direction by automatic. The device could change display directions according to the handling direction. Please refer to chapter "Calibration setting" for detail.

6.1.5 Menu Operations

In the measuring interface, long press button to enter the main menu interface as figure 4 (When the display direction is lengthways, you cannot enter the main menu interface. Please change to landscape orientation.) The user can adjust the settings through the main menu, such as backlight, alarm, direction sensor, data transmission (with the data line). The specific operation methods are as follows:

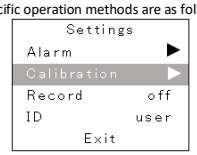


Figure 4 Main Menu Interface

a. Alarm setting

In the main menu interface, short press button to move the choice bar to "Alarm" item, then long press button to enter the alarm setting menu as figure 5:

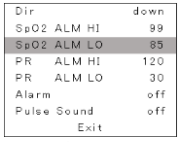


Figure 5 Alarm setting menu

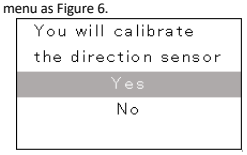
- **The high/low limit of alarm setting**
In alarm setting menu, short press button to move the choice bar to "DIR" item, long press button to choose Up or Down (This will be the direction the value of the high-low limits of SpO_2 and pulse rate will be adjusted). Short press button to adjust alarm item: SpO_2 high limit (SpO_2 ALM HI), SpO_2 low limit (SpO_2 ALM LO), Pulse Rate high limit (PR ALM HI), Pulse rate low limit (PR ALM LO). Long press button to change the value. Long press button once, and the value raise or descend once. The low limit can't be above high limit, and the high limit can't be below the low limit.

⚠ **If the alarm function is on, the device will provide medium-priority alarm signal when the data of SpO_2 or pulse rate is beyond the limit. Intermittent alarm will occur and the values show in yellow. Medium priority indicating that prompt operator response is required.**

- **The alarm indication setting**
  In alarm setting menu, short press button to move the choice bar to the "Alarm" item, then long press button to turn on or turn of the alarm sound. Choose "on" to turn on pulse sound, and choose "off" to turn off the alarm.
- **Pulse sound indication setting**
  In alarm setting menu, short press button to move the choice bar to the "Pulse Sound" item, then long press button to turn on or turn off to turn off pulse sound.
- **Exit operation**
  In alarm setting menu, short press button to move the choice bar to "Exit" item, then long press button to exit alarm setting menu and return to the main menu.

b. Calibration setting

In the main menu interface, short press button to move the choice bar to "calibration" item, then long press button to enter the direction sensor setting menu as Figure 6.



Direction sensor calibration function

When the direction sensor error is larger, the user could use this function to calibrate direction sensor.

In the sensor setting interface, short press button to move the choice bar to "calibration" item. Long press button, the display screen will appear prompt "You will calibrate the direction sensor". If you want to calibrate, please put the device horizontally, then move the choice bar to "yes" item and long press button to affirm. Wait 5 seconds until the display screen appears "Calibrate successfully", here calibrate direction sensor successfully. If prompt "Calibrate unsuccessfully" appears, this calibration is unsuccessful. The user could calibrate again according to the above operation until calibration is successful.

⚠ **When calibrating, please put the device horizontally and stop measuring.**

c. Data record setting

This device can record 24 hours data including pulse rate and SpO_2 value accurately when the battery is full and upload the data to the computer with USB Cable for display and analysis.

- In the main meu interface, short press button to move the choice bar to "Record: item, then long press button to enter the record time setting dialog box as figure 7.

  Time 12:00 Y/N Figure 7 Record time setting dialog box
- Short press button to move the underline to the number that you want to set, then long press button to set time. After setting time, move the underline to "Y", then long press button to set "Record" item as "on" and begin to record. If move the underline to "N", then long press button to cancel record. When recording, long press button to set "record" item as "off", here record function is closed, data is saved.
- If the record function is turned on, a flashing red dot would appear on the screen when returning to the measure interface, which means the device is recording.
- If the device is recording, whatever interface the device is in (measuring interface, menu interface), the sign "Recording" would appear on the screen in 30 seconds, then screen will be automatically shut down. If short press button at this moment, the sign "Recording" would appear on the screen, then the screen will be automatically shut down again; if long press the button, the device would return to the former interface.
- If turning on the record function, the former saved data will be automatically deleted.
- When recording, the pulse sound indication would be turned off for saving power, after the screen is shut down automatically.
- When data storage space is full, it displays "Memory is full" by the next time you turn on the device on the purpose of warning the user.

d. Device ID

The user can modify device ID by software "SpO_2 Assistant".

e. Exit the main menu

In the main menu interface, move the choice bar to "Exit" item, then long press button to exit the main menu and return to the measure interface.

f. PC Software operation

Please connect the device with computer by the USB Cable which is affiliated with the device, then double click "SpO_2 Assistant" icon to run the PC software. The function such as uploading storage data and change device ID can be carried out by the software. Please refer to < SpO_2 Assistant user manual> for details.

⚠ **If the users choose to turn the synchronizing display function on computer, it would probably take several seconds for the data to appear in the computer screen. (if there is no data in the computer screen, unplug the USB Cable, then try again.)**

6.1.6 Charge

There are two kinds of the charge method:

a. Connect the device to computer with USB Cable, then the device should be in charge state.
b. Connect the device to power supply with power adaptor, the device should be in charge state.

⚠ **In the charge state, the blue indication light shining means the device is charging up, the blue indication light quenching means the charge has been accomplished.**

⚠ **If the alarm function is on, the device will provide high-priority alarm signal when the battery is in low power status. Intermittent alarm will occur.**
High priority indicating requires that operator responds immediately.

6.2 Attention for operation

a. Please check the device before using, and confirm that it can work normally.
b. The finger should be in a proper position (see the attached illustration as figure 3 for reference), or else it may result in inaccurate measure.
c. The ray between luminescent tube and photoelectric receiving tube must get across subject's arteriole.
d. The oximeter should not be used at a location or limb tied with arterial canal or blood pressure cuff or receiving intravenous injection.
e. Ensure nothing, such as a plaster, can impede the light passage, or else it may result in inaccurate measure of SPO_2, pulse rate and PI.
f. Excessive ambient light may affect measurement accuracy. It includes fluorescent lamp, dual ruby light, infrared heater, direct sunlight and etc.
g. Intense activity of the subject or extreme electrosurgical interference may also affect the accuracy.
h. Testee cannot use enamel or other makeup.
i. Please clean and disinfect the device after operating according to the user manual (7.1).

6.3 Clinical restrictions

a. As the measure is taken on the basis of arteriole pulse, substantial pulsating blood flow of subject is required. For a subjects with weak pulse due to shock, low ambient / body temperature, major bleeding, or the use of vascular contracting drugs, the SpO_2 waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.
b. For those with a substantial amount of staining dilution drug (such as methylene blue, indigo green and acid indigo blue), or carbon monoxide hemoglobin (COHb), or methionine (Me+Hb) or thiosalicylic hemoglobin, and some of the problems of jaundice, the SpO_2 determination by this monitor may be inaccurate.
c. The drugs such as dopamine, procaine, prilocaine, lidocaine and butacaine may also be the main factor blamed for serious SpO_2 size errors.
d. As the SpO_2 value serves as a reference value for judgment of anemic anoxia and toxic anoxia, some patients with serious anemia also report good SpO_2 measurement.

7 Maintain, transportation and storage

7.1 Cleaning and disinfecting

Using medical alcohol to wipe the device for disinfecting, nature dry or clean it with clean soft cloth.

7.2 Maintain

a. Please clean and disinfect the device before using according to the user manual (7.1)
b. Please recharge the battery when the screen shows low-power (the battery power is)
c. Recharge the battery soon after the over-discharge. The device should be recharged every six months when it is not regular used. It can extend the battery life following this guidance.
d. User are advised to calibrate the device termly (or according to the calibrating program of hospital). It also can be performed at the state-appointed agent or just contact us for calibration.

7.3 Transportation and Storage

a. The packed device can be transported by ordinary conveyance or according to transport contract. The device cannot be transported mixed with toxic, harmful, corrosive material.
b. The packed device should be stored in room with no corrosive gases and good ventilation. Temperature: - 40°C ~ 60°C; relative humidity: ≤95%

8 Troubleshooting

Trouble	Possible Reason	Solution
The SpO_2 and Pulse Rate cannot be displayed normally	The finger is not properly positioned.	Place the finger properly and try again.
	The patient's SpO_2 is too low to be detected.	Try again; Go to a hospital for a diagnosis if you are sure the device works all right.
The SpO_2 and Pulse Rate are not displayed stably	The finger is not placed inside deep enough.	Place the finger properly and try again.
	The finger is shaking or the patient is moving.	Let the patient keep calm
The device cannot be turned on	The battery is drained away or almost drained away	Please charge up battery.
	The malfunction of the device.	Please contact the local service center.
The display is off suddenly	The device is set to shut down automatically in 5 seconds when there is no signal	Normal.
	The battery is drained away or almost drained away	Please charge up battery.
The device cannot be used for full time after charge	The battery is not full charged	Please recharge battery
	The battery is broken	Please contact the local service center
The battery cannot be full charged even after 10 hours charging time	The battery is broken	Please contact the local service center

10 Key of Symbols

Signal	Description
	Refer to instruction manual / booklet
%SpO_2	The pulse oxygen saturation(%)
PRbpm	Pulse rate (bpm)
PI	Perfusion Index (%)
	The battery power is full
	Low-power
	Close the alarm sound indication
	Pause the alarm sound indication
	Open the alarm sound indication
	Close the pulse sound indication
	Open the pulse sound indication
	Menu button/power button/function button
IP22	International Protection
	USB
	WEEE (2002/96/EC)
	Type BF
	Manufacturer
	Date of manufacture
	Storage and Transport Temperature limitation
	Storage and Humidity limitation
	Storage and Atmospheric pressure limitation
	This side up
	Fragile, handle with care
	Keep dry
	Recyclable
SN	Serial number

11 Function Specification

Display Information	Display Mode
The Pulse Oxygen Saturation (SpO_2)	2-Digit digital LCD Display
Pulse Rate(PR)	3-Digit digital LCD Display
Perfusion Index (PI)	3-Digit digital LCD Display
Pulse Intensity (bar-graph)	Bar-graph LCD Display
SpO_2 Parameter Specification	
Measuring range	0%~99%, (the resolution is 1%).
Accuracy	70%~99%:±2%, Below 70% unspecified.
Pulse Parameter Specification	
Measuring range	30bpm~250bpm (the resolution is 1 bpm)
Accuracy	30bpm~100bpm: ±2bpm 101bpm~250bpm: ±2%
Perfusion Index Specification	
Range	0%~20%
Safety Type	**Interior Battery, BF Type**
Pulse Intensity	
Range	Continuous bar-graph display, the higher display indicates the stronger pulse
Battery Requirement	
Voltage 3.7 rechargeable lithium battery x 1 (the red wire on battery denotes anode, the black wire on the battery denotes cathode)	
Battery Working Life	
Charge and discharge no less than 500 times	
Power adapter (selected)	
Output voltage	DC 5V
Output current	1000 mA
Dimensions and Weight	
Dimensions	58(L) × 36(W) × 26(H) mm
Weight	± 45g (with a lithium battery)

Appendix		
State	Alarm condition delay	Alarm signal generation delay
Low-power alarm	1 s	20 ms
SpO2 alarm	330 ms	20 ms
Pulse rate alarm	330 ms	20 ms
Probe error alarm	16 ms	20 ms

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